Docket No.: 511582000100
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Aya JAKOBOVITS et al.

Application No.: 09/771,312 Confirmation No.: 7650

Filed: January 26, 2001 Art Unit: 1642

For: 84P2A9: A PROSTATE AND TESTIS SPECIFIC PROTEIN HIGHLY EXPRESSED IN PROSTATE CANCER Examiner: B. Fetterolf

APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

As required under § 41.37(a), this brief is filed more than two months after the Notice of Appeal filed in this case on August 7, 2007, and is in furtherance of said Notice of Appeal. Filed herewith is a Petition and a fee for a five-month extension of time, thereby extending the deadline to March 7, 2008.

The fees required under § 41.20(b)(2) are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

This brief contains items under the following headings as required by 37 C.F.R. § 41.37 and M.P.E.P. § 1206:

I. Real Party In Interest
II Related Appeals and Interferences
III. Status of Claims

I. REAL PARTY IN INTEREST

The real party in interest for this appeal is Agensys, Inc., having its principal place of business at 1545 17th Street, Santa Monica, CA 90404.

II. RELATED APPEALS, INTERFERENCES, AND JUDICIAL PROCEEDINGS

There are no other appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

A. Total Number of Claims in Application

There are 4 claims pending in application. The claims on appeal are claims 12, 14, 15, and 39.

B. Current Status of Claims

1. Claims canceled: 1-11, 13, 16-38, and 40-48

2. Claims withdrawn from consideration but not canceled: None

3. Claims pending: 12, 14, 15, and 39

4. Claims allowed: None

5. Claims rejected: 12, 14, 15, and 39

C. Claims on Appeal

The claims on appeal are claims 12, 14, 15, and 39.

IV. STATUS OF AMENDMENTS

Applicant filed an Amendment After Final Rejection on August 7, 2007. The Examiner responded to the Amendment After Final Rejection in an Advisory Action mailed September 6, 2007. In the Advisory Action, the Examiner indicated that Applicants' proposed amendments to claims would be entered.

Accordingly, the claims in Appendix A incorporate the amendments indicated in the paper filed by Applicant on August 7, 2007.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The subject matter of the pending claims relates to a novel gene and its encoded protein, termed 84P2A9. Evidence provided in the Specification indicates that this gene and its encoded protein are expressed by both normal and cancerous prostate cells. Specification, page 14. The subject matter of the claims specifically relate to amino acid sequences encoded by polynucleotides corresponding or complementary to all or part of an 84P2A9 gene, mRNA, and/or coding sequence. Specification, page 18. They also relate to an isolated recombinant protein comprising the amino acid sequence encoded by those polynucleotides. Specification, page 26. Applicants have asserted

that the claimed protein is useful to treat prostate cancer, for example, by serving as a target for antibodies on prostate cancer cells. Amendment After Final Action, page 4. The claimed protein is asserted as a useful target on cancer cells regardless of the protein expression levels compared to normal cells.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The sole issue on appeal is whether the subject matter of the pending claims is supported by either a credible, specific, and substantial asserted utility, or a well-established utility pursuant to 35 U.S.C. § 101. The companion rejection of these claims under 35 U.S.C. § 112 for an alleged lack of enablement depends entirely on the rejection under 35 U.S.C. § 101. Thus, resolution of the utility rejection simultaneously resolves the rejection for an alleged lack of enablement.

VII. ARGUMENT

A. Applicants have asserted a credible, specific, and substantial utility, which is supported by experimental data presented in the specification and during prosecution

For the purposes of prosecution and now for the present appeal, Applicants assert that the protein comprising the amino acid sequence of SEQ ID NO:2 serves as a marker on cancerous prostate cells and is useful as a therapeutic target for antibodies directed against such cancer cells.

As a preliminary matter, Applicants note that Examiner acknowledges and agrees with the legal requirements for utility and enablement that "applicants need only assert a single credible assertion of specific utility of the claimed invention to satisfy the utility requirement." Advisory Action, page 6. In fact, "[an] applicant need only make one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. § 101 and 35 U.S.C. § 112; additional statements of utility, even if not 'credible,' do not render the claimed invention lacking in utility." M.P.E.P § 2107.02, citing *Raytheon v. Roper*, 724 F.2d 951, 958, 220 USPQ 592, 598 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 835 (1984). Applicants assert that the protein comprising the amino acid sequence of SEQ ID NO:2 is a marker on cancerous prostate cells and is useful as a therapeutic target for antibodies directed against such cancer cells.

The Specification is replete with explicit assertions regarding the utility of the claimed novel gene and its encoded protein, 84P2A9, for the treatment of prostate cancer. For example, the Specification includes an entire section discussing therapeutic methods and compositions. These methods generally fall into two classes. One class comprises various methods for inhibiting the binding or association of the 84P2A9 protein with its binding partner or with other proteins. The other class comprises a variety of methods for inhibiting the transcription of the 84P2A9 gene or translation of 84P2A9 mRNA. Specification, page 55. Examples which fall within these two categories are discussed in pages 55 through 64 of the Specification.

The assertion of even a single, legally sufficient utility is enough to satisfy the statutory requirement. *See, e.g., Raytheon v. Roper*, 724 F.2d 951, 958 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 835 (1984) ("When a properly claimed invention meets at least one stated objective, utility under 35 U.S.C § 101 is clearly shown."); M.P.E.P. § 2107.02.

The cited portions of the Specification provided above clearly indicate that Applicants have asserted at least one use for the claimed subject matter.

B. Applicants have provided sufficient evidence to demonstrate the utility of the claimed invention

To satisfy the utility requirement, an applicant need only supply enough evidence to convince one of ordinary skill in the art that there exists a "sufficient likelihood" that the claimed invention possesses the asserted utility. *See, e.g. Brenner v. Manson*, 383 U.S. 519, 532 (1966); *In re Jolles*, 628 F.2d 1322, 1326 (CCPA, 1980) *citing In re Irons*, 340 F.2d 974 (CCPA, 1965) ("Proof of utility is sufficient if it is convincing to one of ordinary skill in the art."). "The amount of evidence required depends on the facts of each individual case. The character and amount of evidence needed may vary, depending on whether the alleged utility appears to accord with or to contravene established scientific principles and beliefs." *Id. (citations omitted).*

As discussed below, Applicants have clearly met this standard; Applicants have provided sufficient evidence to convince one of ordinary skill in the art that the presently claimed invention is useful for its intended purpose.

1. Evidence of Utility in the Specification -- Nexus of Claimed Protein and Prostate Cancer

Applicants have provided more than sufficient evidence to support the asserted utility for the claimed invention. The protein comprising the amino acid sequence of SEQ ID NO:2 is useful as a therapeutic target for antibodies directed against cancer cells, because it is expressed as a marker on cancerous prostate cells.

Applicants have previously provided evidence which demonstrated that the claimed protein is expressed by cancerous prostate cells. Applicants demonstrated this by providing evidence of increased mRNA expression in various cancer tissue lines. The data in Figures 4 and 5 show high levels of 84P2A9 mRNA expression in prostate cancer tissues. *See also*, Specification, page 75. Figure 6 presents data from prostate cancer patients, showing expression of 84P2A9 mRNA in both the normal and tumor part of the prostate tissues. *See also*, Specification, page 76. Taken together these results suggest that 84P2A9 is a very testis-specific gene that is up-regulated in prostate cancer and potentially other cancers. *Id.*

The showing of increased 84P2A9 mRNA expression is sufficient to establish a specific and substantial utility for the polypeptide of SEQ ID NO: 2 because there is a strong correlation between mRNA levels and protein expression. Contrary to the Examiner's allegation that in order to establish utility the Specification needs to disclose a correlation between a specific disorder and an altered level or form of the claimed polypeptide, a correlation between a specific disorder and polynucleotide levels is sufficient. As discussed above, the Specification provides more than enough evidence of increased levels of 84P2A9 mRNA expression in prostate cancer and other tumor tissues. Accordingly, one of ordinary skill in the art could conclude reasonably that the claimed protein is expressed in prostate cancer cells.

A recent decision by the Board of Patent Appeals and Interferences ("Board") affirmed this exact standard. The Applicants in *Ex parte Audrey Goddard, Paul J. Godowki, Austin L. Gurney, Victoria Smith, and William I. Wood* (2007) Application No. 10/123,212, Appeal No. 2006-1469, presented microarray data in their Specification which, according to the Examiner, measured "mRNA levels, and not overexpression of the polypeptide... itself" *Ex parte Goddard*, page 9. The Board accepted the Examiner's assertion, but did not accept it as a reason to reject Applicants' claims. Rather, the Board found that because "there is a strong correlation between mRNA levels and protein expression," it could conclude that "the microarray data presented... [in] the Specification [was] sufficient to establish a specific an substantial utility for the polypeptide [in the claims]." *Id.*

The type of data addressed by the Board in *Ex Parte Goddard* is identical to the data presented by Applicants here. The data in *Ex Parte Goddard* demonstrated that "mRNA for the PRO18666 polypeptide (SEQ ID NO:14) is overexpressed in colon tumor, prostate tumor, lung tumor [sic], as compared to universal normal control." The Board concluded, therefore, that "the polypeptide... has a significant and presently available benefit to the public as a tumor marker" *Ex Parte Goddard,* page 9. The increased levels of mRNA expression for the 84P2A9 polypeptide in prostate cancer and other tumor tissues shown in Figures 4 through 6 of the Specification lead to the same conclusion, that the encoded polypeptide has a significant and presently available benefit to the public as a tumor marker.

2. Evidence of Utility Provided During Prosecution

In addition to the data disclosed in the Specification which indicates the utility of the claimed invention, Applicants provided declaratory evidence in support of the asserted utility during the prosecution of the present case. Applicants provided a Rule 1.132 declaration of Dr. Morrison with its October 12, 2005 response, demonstrating that antibodies which bind to the claimed protein are capable of binding to prostate cancer cells. Dr. Morrison's declaration reported immunohistochemistry data where prostate tumor samples were tested with a polyclonal rabbit anti-84P2A9 antibody. The staining of the tumor samples clearly showed that the claimed protein is

produced in prostate cancer and can be detected by immunohistochemistry as set forth in the Specification. Specifically, the 84P2A9 protein was detected n the cytoplasm and the cell surface, indicating that the protein is associated with the membrane. Therefore, Dr. Morrison's declaration provides clear support for Applicants' assertion that the expressed protein is useful as a therapeutic target for antibodies directed against such cancer cells.

In view of the above, Applicants submit that declaratory evidence provided during prosecution supports Applicants' assertion of utility.

C. The Asserted Utility is Credible, Specific, and Substantial

Once a utility has been asserted the Office has the initial burden to establish whether a skilled artisan would consider the asserted utility to be credible, specific, and substantial. *See In re Brana* at 1566. The Examiner has failed to meet this initial burden. Nevertheless, Applicants describe in detail below how the asserted utility for the claimed invention is credible, specific, and substantial.

1. Credible Utility

"To violate [35 U.S.C.] 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, (Fed. Cir. 1992) (emphasis added). As discussed in the M.P.E.P. at section 2107.01, situations where an invention is completely inoperative are rare and examples where the rejection has been upheld on appeal are rarer still. The Examiner alleged that the asserted utility is not credible, but has not stated why one of ordinary skill in the art would believe that the invention was completely inoperative. The data provided in the Specification as well as by declaratory evidence shows that antibodies made against the protein of interest are capable of binding to prostate cancer cells. Thus, there is more than sufficient evidence to support the asserted utility.

The Examiner alleged that because target protein is expressed on both normal and cancerous prostate cancer cells, one of ordinary skill in the art would doubt the usefulness of the

claimed antibodies. As previously asserted by Applicants, questions relating to expression levels of the claimed protein on normal cells are not relevant to the issue of utility because Applicants have demonstrated that the claimed protein is detected on cancerous prostate cells. The Morrison declaration supports this argument. Additionally, the loss of normal prostate cells while eliminating cancerous prostate cells is inconsequential from the point of evaluating utility because the point of prostate cancer therapy is to eliminate prostate cancer cells. Given the disposable nature of the prostate organ, the expression of the protein by both normal and cancerous prostate cells would not be viewed by those of ordinary skill in the art as being detrimental to the utility of the claimed proteins. Therapies involving antibodies that recognize the claimed protein, as one specific example, would recognize both cancerous and normal cells. In view of this showing, Applicants submit that those of ordinary skill in the art would, more likely than not recognize the presently asserted utility as credible.

2. Specific Utility

Applicants have presented data that the claimed proteins are expressed by prostate cancer cells. Thus, this protein can be used to as a target for cells that express it. Because the protein is expressed on the cell membrane of cancerous prostate cells, antibodies that recognize that protein will target those cancerous prostate cells. In view of the specific relationship existing between the protein and it presence on cancerous prostate cells, the presently asserted utility for the claimed antibodies as a treatment for prostate cancer is sufficiently specific to satisfy this prong of the test.

3. Substantial Utility

A substantial utility is one that defines a "real world" or a "practical" use. *In re Brana* at 1371; MPEP §2107.01. "'Practical utility' is a shorthand way of attributing 'real-world' value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public." *Nelson v. Bowler,* 626 F.2d 853, 856 (C.C.P.A. 1980). Any reasonable use asserted by an applicant that provides a public benefit "should be accepted as sufficient, at least with regard to defining a 'substantial' utility." MPEP

§2107.01, *see also Nelson* at 856. Moreover, "[k]nowledge of the pharmacological activity of any compound is obviously beneficial to the public." *Nelson* at 856.

There is no doubt that the presently claimed protein has substantial utility because it is a target for treating cancerous prostate cancer cells. Further, there is nothing in the record or in the art as a whole that would lead one of ordinary skill in the art to think that the presently claimed invention lacks a substantial utility. As discussed above, the Board has interpreted data showing polynucleotide expression as a sufficient correlative to protein expression. In view of the data provided in the Specification as well as the art-recognized need for additional prostate cancer markers, Applicants submit that the Specification clearly asserts a substantial utility for the claimed invention.

The Examiner alleged, for example in the Advisory Action, that there is evidence that the target protein could be expressed in both normal and cancerous prostate. The Examiner goes on to allege that one of ordinary skill in the art would not be able to use the claimed antibodies to treat prostate cancer if there is not differential expression of the target protein between normal and cancerous prostate cells. Applicants disagree with the Examiner. Differential expression of the 84P2A9 protein is not required for the claimed invention to be useful, as discussed *supra*.

CONCLUSION

The threshold for utility is not high under 35 U.S.C. § 101; an invention is useful if it is merely capable of providing some identifiable benefit. *Juicy Whip, Inc. v. Orange Bang, Inc.*, 51 U.S.P.Q.2d 1700, 1702 (Fed Cir. 1999) (citing *Brenner v. Manson*, 383 U.S. 519, 534 (1966)). Applicants have satisfied the statutory requirement for demonstrating that the claimed invention is useful. Evidence supporting the utility of the invention is present both in the Specification as filed as well as in the prosecution history. The evidence proffered is more than adequate to support the utility asserted by Applicants. As such, the Board is respectfully requested to overturn the present rejection and advance the case to issuance.

VIII. CLAIMS APPENDIX

A copy of the claims involved in the present appeal is attached hereto as Appendix A. As indicated above, the claims in Appendix A include the amendments filed by Applicant on August 7, 2007.

IX. EVIDENCE APPENDIX

A copy of the Morrison a Declaration is provided at Appendix B. This evidence was made of record in conjunction with the response filed on October 12, 2005. The Examiner noted the declaration in the Office Action mailed on January 13, 2006.

X. RELATED PROCEEDINGS

No related proceedings are referenced in II. above, or copies of decisions in related proceedings are not provided, hence no Appendix is included.

Dated: March 7, 2008

Respectfully submitted,

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APPENDIX A

Claims Involved in the Appeal of Application Serial No. 09/771,312

12. An isolated recombinant protein comprising the amino acid sequence of SEQ ID NO:2.

14. An isolated recombinant protein that has an amino acid sequence encoded by a polynucleotide selected from the group consisting of:

(a) a polynucleotide having the sequence as shown in SEQ ID NO:1, wherein T can also be U;

(b) a polynucleotide having the sequence as shown in SEQ ID NO:1, from nucleotide residue number 163 through nucleotide residue number 1674, wherein T can also be U;

(c) a polynucleotide encoding a protein whose sequence is encoded by the cDNAs contained in the plasmids designated p84P2A9-1 deposited with American Type Culture Collection as Accession No. PTA-1151; and

(d) a polynucleotide encoding a protein having the amino acid sequence shown in SEQ ID NO:2.

15. The isolated recombinant protein of claim 14, wherein the recombinant protein is encoded by a polynucleotide comprising the sequence as shown in SEQ ID NO:1, from nucleotide residue number 720 through nucleotide residue number 1392.

39. A pharmaceutical composition comprising a recombinant protein, wherein the protein comprises the amino acid sequence of SEQ ID NO: 2, and a physiologically acceptable carrier.